

2 510(k) Summary of Safety and Effectiveness

Date Summary Prepared	February 15, 2013
Manufacturer/Distributor/Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Christina Flores Regulatory Affairs Specialist Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239-643-5553, ext. 1819 Fax: 239-569-5508 Email: Christina.flores@arthrex.com
Trade Name	<i>Knotless FiberTak Suture Anchor</i>
Common Name	Soft Tissue Fixation Device
Product Code	MBI
Classification Name	Fastener, fixation, nondegradable, soft-tissue
CFR	21 CFR 888.3040
Predicate Device	<i>K120155: Arthrex Knotless SutureTak</i> <i>K041553: Arthrex FiberWire</i> <i>K110145 Biomet JuggerKnot™ Soft Anchors</i>
Purpose of Submission	This traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Knotless FiberTak Suture Anchor, to expand the Arthrex SutureTak family of anchors.
Device Description and Intended Use	<p>The Arthrex <i>Knotless FiberTak Suture Anchor</i> is an "all-suture" soft-tissue fixation device with an expandable push-in design. It is constructed from a hollow braid of polyester. An UHMWPE suture construct is assembled through the hollow braid coupled with a nitinol passing wire. The device comes preloaded on a disposable inserter.</p> <p>The Arthrex Knotless FiberTak is intended for fixation in the foot, ankle, knee, hand, wrist, elbow, shoulder, and hip. Specific indications are listed below:</p> <p><i>Elbow:</i> Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction</p> <p><i>Shoulder:</i> Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular</p>



	<p>Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction</p> <p><i>Hand/Wrist:</i> Scapholunate Ligament Reconstruction, Carpal Ligament Reconstructions, Repair/Reconstruction of collateral ligaments; Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP joints for all digits, Digital Tendon Transfers</p> <p><i>Foot/Ankle:</i> Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, Digital Tendon Transfers, Mid-foot Reconstruction</p> <p><i>Knee:</i> Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis</p> <p><i>Hip:</i> Acetabular Labral repair</p>
<p>Substantial Equivalence Summary</p>	<p>The <i>Arthrex Knotless FiberTak Suture Anchor</i> is substantially equivalent to the predicate devices, in which the basic design features and intended uses are the same. Any differences between the <i>Arthrex Knotless FiberTak</i> and the predicates are considered minor and do not raise questions concerning safety and effectiveness.</p> <p>The proposed devices are comprised of polyester and UHMWPE. These materials are substantially equivalent to the materials found in the predicate devices.</p> <p>The submitted mechanical testing data demonstrates that the tensile strength (pull-out) of the proposed devices are substantially equivalent to the predicates for the desired indications.</p> <p>Based on the indication for use, technological characteristics, and the summary of data submitted, Arthrex, Inc. has determined that the <i>Knotless FiberTak Suture Anchor</i> is substantially equivalent to currently marketed predicate devices.</p>



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 3, 2013

Arthrex, Incorporated
% Ms. Christina Flores
Regulatory Affairs Specialist
1370 Creekside Boulevard
Naples, Florida 34108

Re: K130458

Trade/Device Name: Arthrex Knotless FiberTak Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Fastener, fixation, nondegradable, soft tissue
Regulatory Class: Class II
Product Code: MBI
Dated: April 22, 2013
Received: April 24, 2013

Dear Ms. Flores:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1 Indications for Use Form

Indications for Use

510(k) Number (if known): K130458

Device Name: *Arthrex Knotless FiberTak Suture Anchor*

Indications For Use:

The *Arthrex Knotless FiberTak Suture Anchor* is intended for suture or tissue fixation in the foot, ankle, knee, hand, wrist, elbow, shoulder, and hip. Specific indications are listed below:

- | | |
|--------------------|--|
| <i>Elbow:</i> | Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction |
| <i>Shoulder:</i> | Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction |
| <i>Hand/Wrist:</i> | Scapholunate Ligament Reconstruction, Carpal Ligament Reconstructions, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP joints for all digits, Digital Tendon Transfers |
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| <i>Knee:</i> | Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis |
| <i>Hip:</i> | Acetabular Labral repair |

Prescription Use ☒ AND/OR Over-The-Counter Use ☐
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Casey L. Hanley, Ph.D.
Division of Orthopedic Devices